

REMARKS

As a result of the Final Office Action mailed on June 16, 2004, Applicant has amended claims 1, 12, and 20 in its response and has added new claims 21-22. Thus, claims 1-13 and 20-22 are pending in this application. New claims 21-22 and the amendments to claims 1 and 12 are fully supported by the original specification as filed, for example, at paragraph [0021] of the publication. The amendment to claim 20 was simply to correct a typographical error. No new matter has been added. Applicants therefore respectfully request that the Amendments be entered.

Applicant's counsel appreciates the courtesies extended by Examiner Leon B. Lankford, Jr. during a telephonic interview on July 22, 2004. Applicants have now amended the claims as agreed during the interview and therefore respectfully request that all the claims be allowed.

Claims 1-7 and 9-12 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jetten *et al.* or Steinberg *et al.* or Hronis *et al.* or Morris *et al.* for the reasons set forth on pages 3-5 of the final Office Action.

The presently claimed invention is directed to retroviral-infected immortalized human keratinocyte or melanocyte cell lines prepared by infection with a retroviral construct under conditions such that immortalizes cells, which cells retain the ability of the cell line to differentiate and to express proteins and enzyme expressed by normal differentiated keratinocytes or melanocytes even after as least 20 passages in tissue culture. New claims 21-22 further require the normal expression and differentiation of the cell line even after at least 30 and 50 passages in tissue culture, respectively.

It was Applicants that first discovered and taught a method of obtaining these retroviral-infected immortalized human keratinocyte or melanocyte cell lines.

The prior art cell lines, in contrast, lost the ability of normal differentiation and expression after only a few passages in culture, which limited their use in research. Jetten *et al.*, for example, were not able to differentiate after more than 12 passages. Steinberg *et al.*, lost the ability of normal keratin expression after about 10-15 passages, as did Hronis *et al.* and Morris *et al.* None of these references, alone or combined, teach Applicants' presently claimed cell line, or method of producing them, which retain normal differentiation and expression even after at least 20 passages. See paragraphs [0007-0008] of US Patent Application Publication 2002/0042129.

These statements are further supported by the Boukamp *et al.* reference (immortalization of keratinocytes using spontaneous immortalization techniques with no retroviral construct) the Examiner previously cited. Boukamp *et al.* actually summarizes the problems with prior art retroviral immortalization techniques prior to Applicants' invention. Boukamp *et al.* states that the prior art retroviral "cells [] exhibited altered growth properties and substantial reduction of normal keratinization as well as partial reexpression of fetal characteristics" concluding that the "deficiencies in differentiation are invariably associated with transformation and/or malignancy. " Boukamp *et al.* taught that the presently claimed cell lines were not possible to produce. In contrast, Applicants have now discovered and teach in the present application methods of producing cell lines that retain normal expression even after at least 20 passages in tissue culture and provide examples of such cell lines.

One skilled in the art would not be motivated or enabled to make Applicants' presently claimed retroviral-infected cell line without the inventors' disclosure.

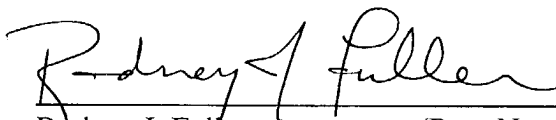
In view of the deficiencies of the cited references and the state of the art at the time of the invention, Applicants respectfully request that this rejection be withdrawn.

In view of the foregoing remarks and amendments, it is believed that the entire application is now in condition for allowance. Should any issues remain, please call Allan Fanucci at (212) 294-3311 or Rodney Fuller at (202) 371-5838 in order to expedite the allowance of all the claims in this application.

Respectfully submitted,

Date

8/4/04



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